

REMARKS

Upon entry of the present amendment, claims 4, 6-8, 10, 12-14, and 16-19 will be pending in the above-identified application and stand ready for further action on the merits.

In this Amendment, claims 1-3, 5, 9, 11, 15, and 20-21 have been cancelled, and claims 4, 7-8, 10, 13-14, and 17-18 have been amended. Support for the amendments to claims 4, 10, 13, and 14 can be found in the present specification, *inter alia*, at page 17, lines 17-19. Claims 7-8 have been amended to depend from claim 4. Claims 17-18 have been amended to depend from claim 14.

Accordingly, the present amendments to the claims do not introduce new matter into the application as originally filed. As such, entry of the present amendment and favorable action on the merits are earnestly solicited at present.

Issues under 35 U.S.C. § 101 and 35 U.S.C. § 112

1) The Examiner has rejected claims 20-21 under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps in the process, results in an improper definition of a process.

2) The Examiner has also rejected claims 11 and 20-21 under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 11 and 20-21 have been cancelled herein, which renders the rejections moot. Accordingly, Applicants respectfully request that the rejections be removed.

Issues under 35 U.S.C. § 102

1) The Examiner has rejected claims 1-9 and 13-21 under 35 U.S.C. § 102(b) as being anticipated by Montgomery '341 (US 6,221,341). Claims 1-3, 5, 9, 15, and 20-21 have been cancelled herein, which renders the rejection as to these claims moot. With respect to the remaining claims, Applicants respectfully traverse. Reconsideration and withdrawal of the rejection are respectfully requested.

Legal Standard for Determining Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsisssimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;

- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

Distinctions over the Cited Art

Independent claims 4, 13, and 14 all recite a pH value of 1 to 5.

In stark contrast, Montgomery ‘341 discloses the importance of a pH value *above* 5.5. Montgomery ‘341 recites, “Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization” (col. 2, lines 25-29). Thus, Montgomery ‘341 fail to disclose a pH value of 1 to 5 as recited in independent claims 4, 13, and 14.

Accordingly, the present invention is not anticipated by Montgomery ‘341 since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Montgomery '341 does not render the present invention obvious because the reference provides no disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

2) The Examiner has rejected claims 1-9, 13-18, and 20-21 under 35 U.S.C. § 102(b) as being anticipated by Speed et al. '564 (US 6,399,564). Claims 1-3, 5, 9, 15, and 20-21 have been cancelled herein, which renders the rejection as to these claims moot. With respect to the remaining claims, Applicants respectfully traverse. Reconsideration and withdrawal of the rejection are respectfully requested.

As noted above, independent claims 4, 13, and 14 all recite a pH value of 1 to 5.

In stark contrast, Speed et al. '564 fail to provide any disclosure about a sterilizer composition having a pH value of 1 to 5. In fact, the Examiner relies on Examples A and B of Speed et al. '564 to teach some of the limitations of the present claims but also relies on the disclosure of a rinse aid composition to disclose other limitations. However, Examples A and B relate to a completely different embodiment that does not include the rinse aid composition. Speed et al. '564 recite, "The detergent tablets of the present invention are preferably not formulated to have an unduly high pH, in preference having a pH measured as a 1% solution in distilled water of from 8.0 to 12.5..." (col. 48, lines 55-60). As such, the embodiment of Examples A and B would not have a pH below 8.0.

Even if the rinse aid composition were included, Speed et al. '564 state, "The pH of the rinse aid composition is preferably less than 7." However, Speed et al. '564 provide no disclosure regarding the pH value of the detergent tablet as a whole. Thus, Speed et al. '564 fail to disclose a pH value of 1 to 5 for a sterilizer composition.

Accordingly, the present invention is not anticipated by Speed et al. '564 since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Speed et al. '564 do not render the present invention obvious because the reference provides no disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

Issues under 35 U.S.C. § 103(a)

1) The Examiner has rejected claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Montgomery '341 in view of Karlson '159 (US 4,517,159).

2) The Examiner has rejected claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Speed et al. '564 in view of Karlson '159.

Claim 11 has been cancelled herein, which renders the rejections as to this claim moot. With respect to the remaining claims, Applicants respectfully traverse. Reconsideration and withdrawal of the rejections are respectfully requested.

As discussed above, neither Montgomery '341 nor Speed et al. '564 disclose the step of "adjusting the reaction system to pH 1 to 5," as recited in independent claim 10, from which claim 12 depends. Applicants respectfully submit that Karlson '159 does not overcome the deficiencies of this reference.

To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be disclosed by the prior art. As discussed above, the cited references fail to disclose all the claim limitations of independent claim 10, and claim 12 dependent thereon. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejections is respectfully requested.

For the reasons given above, the combination of references does not render the present invention obvious because the cited references do not disclose at least one feature of the present invention and its effects. Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 4, 6-8, 10, 12-14, and 16-19 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 
John W. Bailey

BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant